

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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RENEE MASCUNANA, :

Plaintiff, :

-against- :

JOHNSON & JOHNSON, JOHNSON & JOHNSON &
JOHNSON PHARMACEUTICAL
RESEARCH & DEVELOPMENT, L.L.C. f/k/a :
R.W. JOHNSON PHARMACEUTICAL
RESEARCH INSTITUTE, and ORTHO- :
McNEIL PHARMACEUTICAL, INC., :

Defendants. :

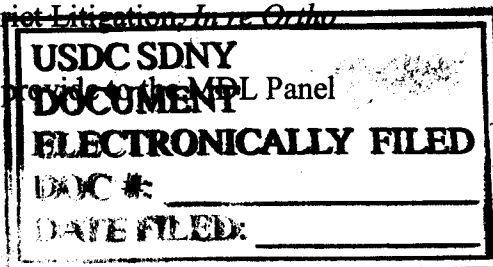
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CASE NO. **07 CIV 7626**

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that defendants Johnson & Johnson, Johnson & Johnson
Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc.
(collectively, "Defendants") hereby remove this action pursuant to 28 U.S.C. §§ 1332 and
1446 from the Supreme Court of the State of New York, Westchester County, to the United
States District Court for the Southern District of New York and respectfully state to this Court
the following:

1. This action involves allegations regarding the prescription contraceptive drug
Ortho Evra®. On March 1, 2006, the Judicial Panel on Multidistrict Litigation issued an order
transferring Ortho Evra® products liability cases to the United States District Court for the
Northern District of Ohio (Katz, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407.
Defendants intend to seek the transfer of this action to that Multidistrict Litigation, *In re: Ortho*
Evra Products Liability Litigation, MDL No. 1742, and will shortly provide to the MDL Panel



notice of this action pursuant to the “tag-along” procedure contained in the MDL Rules.

2. Plaintiff Renee Mascunana (“Plaintiff”) filed this civil action against Defendants in the Supreme Court of the State of New York, Westchester County, bearing Index Number 07-14999 on August 14, 2007. Defendants were served with the complaint on August 23, 2007. A true and correct copy of the Summons and Complaint is attached hereto as Exhibit A.

3. Plaintiff asserts a claim for damages allegedly arising out of her use of the prescription contraceptive patch, Ortho Evra®. Plaintiff alleges “severe and permanent physical injuries, including but not limited to pulmonary embolism.” (See Ex. A, Complaint, ¶ 97.) Plaintiff’s claims are based on theories of strict liability, failure to warn, negligence, and breach of warranty. Plaintiff demands \$5 million for each claim asserted. (*Id.*) Plaintiff also seeks punitive damages. (See Ex. A, Complaint at 18.)

4. As more fully set out below, this case is properly removed to this Court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 because Defendants have (1) satisfied the procedural requirements for removal and (2) this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332.

I. DEFENDANTS HAVE SATISFIED THE PROCEDURAL REQUIREMENTS FOR REMOVAL.

5. Plaintiff’s Complaint (“Complaint”) was filed on August 14, 2007. Defendants were served with the Complaint on August 23, 2007. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1441. Venue is proper in this Court pursuant to 28 U.S.C. § 89 (c) because it is the “district and division embracing the place where such action is pending.” See 28 U.S.C. § 1441(a).

6. All defendants consent to this removal.

7. No previous application has been made for the relief requested herein.

8. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served upon counsel for Plaintiff and a copy is being filed with the Clerk of the Court for the Supreme Court of the State of New York, Westchester County.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action in which the amount in controversy exceeds the sum of \$75,000, exclusive of costs and interest and is between citizens of different states.

A. Complete Diversity Of Citizenship

10. There is complete diversity between Plaintiff, a citizen of New York,¹ and defendants, citizens of New Jersey and Delaware, the only parties to this action.

11. Upon information and belief, Plaintiff is and was at the time she commenced this action a citizen of the State of New York.

12. Johnson & Johnson is, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the State of New Jersey, with its principal place of business in New Brunswick, New Jersey and, therefore, is a citizen of New Jersey for purposes determining diversity. 28 U.S.C. § 1332(c)(1).

13. Johnson & Johnson Pharmaceutical Research & Development, L.L.C. is a limited liability company organized under the laws of the State of New Jersey, with its principal place of business in Raritan, New Jersey, and, therefore, is a citizen of New Jersey for purposes of determining diversity. 28 U.S.C. § 1332(c)(1).

¹ Plaintiff alleges that she currently resides in the State of New York, Westchester County. (Compl., ¶ 1). Plaintiff alleges no other alternative state of residence. Accordingly, New York is the state in which Plaintiff is domiciled and, therefore, the state of which she is a citizen. See 28 U.S.C. § 1332(a); see also *Linardos v. Fortuna*, 157 F.3d 945, 946 (2d Cir. 1998) (“[f]or purposes of diversity jurisdiction, a party’s citizenship depends on her domicile.”).

14. Ortho-McNeil Pharmaceutical, Inc. is, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the State of Delaware, with its principal place of business in Raritan, New Jersey and, therefore, is a citizen of Delaware and New Jersey for purposes determining diversity. 28 U.S.C. § 1332(c)(1).

B. The Amount In Controversy Requirement Is Satisfied.


15. The Complaint alleges that Plaintiff suffered personal injuries due to her use of the Ortho Evra® patch, and she demands \$5 million for each claim asserted. Accordingly, there is no genuine issue that the amount in controversy exceeds \$75,000, exclusive of interest and costs.

WHEREFORE, Defendants respectfully remove this action from the Supreme Court of the State of New York, Westchester County, pursuant to 28 U.S.C. § 1441.

Dated: New York, New York.
August 27, 2007

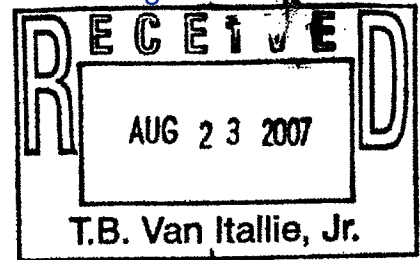
Respectfully submitted,

DECHERT LLP

By: 
Robert W. Sparks (RS 4250)
Debra D. O'Gorman (DO 1643)
Patrick G. Broderick (PB 9556)

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Attorneys for Defendants Johnson & Johnson,
Johnson & Johnson Pharmaceutical Research
and Development, L.L.C., and Ortho-McNeil
Pharmaceutical, Inc.



SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

----- X
RENEE MASCUNANA,

Plaintiff,

v.

JOHNSON & JOHNSON, JOHNSON &
JOHNSON PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C. f/k/a R.W.
JOHNSON PHARMACEUTICAL RESEARCH
INSTITUTE, and ORTHO-MCNEIL
PHARMACEUTICAL, INC.,

Defendants.
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Index No.: 14999/07

Date Purchased: 8/14/07

Plaintiff designates WESTCHESTER
County as the place of trial based
upon Plaintiffs' residence

SUMMONS

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiffs' attorneys within twenty (20) days after service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: New York, NY
August 13, 2007

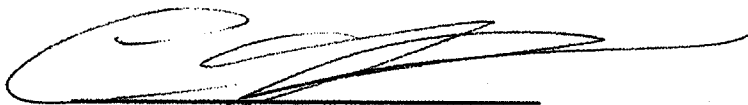
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Defendants' business addresses:

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Johnson & Johnson Pharmaceutical Research & Development, L.L.C., f/k/a R.W.
Johnson Pharmaceutical Research & Development, L.L.C.)
920 Route 202 South
PO Box 300
Mail Stop 2628
Raritan, NJ 08869

Ortho-McNeil Pharmaceutical, Inc.
1000 Route 202 South, P.O. Box 300
Raritan, NJ 08869



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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

RENEE MASCUNANA

Plaintiffs,

v.

JOHNSON & JOHNSON, JOHNSON &
JOHNSON PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C. f/k/a R.W.
JOHNSON PHARMACEUTICAL RESEARCH
INSTITUTE, and ORTHO-MCNEIL
PHARMACEUTICAL, INC.

Defendants.

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Index No.:

**VERIFIED COMPLAINT AND
DEMAND FOR JURY TRIAL**

Plaintiff RENEE MASCUNANA, by and through her attorneys, Napoli Bern Ripka &
Associates, LLP, allege upon information and belief, as follows:

THE PARTIES

1. At all times relevant hereto, the Plaintiff, RENEE MASCUNANA (hereinafter referred to as "Plaintiff"), was and still is a resident of the County of Westchester, State of New York.

2. The Defendant JOHNSON & JOHNSON, is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

3. At all times material hereto, the Defendant JOHNSON & JOHNSON, was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling the combination transdermal birth control patch known as ORTHO EVRA® (hereinafter referred to as "ORTHO EVRA" or "the subject product").

4. The Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, (hereinafter referred to as "JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.") is a limited liability company organized under the laws of New Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

5. At all times material hereto, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

6. The Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., is part of the Defendant JOHNSON & JOHNSON'S "Family of Companies".

7. Upon information and belief, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., was formed by a 2001 merger of The Janssen Research Foundation and the R.W. Johnson Pharmaceutical Research Institute.

8. The Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., is a Delaware corporation which has its principle place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

9. At all times material hereto, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

10. The Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC. is a wholly owned subsidiary of the Defendant, JOHNSON & JOHNSON.

FACTUAL ALLEGATIONS

11. ORTHO EVRA is a transdermal contraceptive patch designed to prevent pregnancy.

12. The Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., describes itself as a “pioneer and leader in contraception and women’s health care, offering the broadest range of prescription birth control options, including the first transdermal contraceptive patch, ten birth control pills and diaphragms.”

13. ORTHO EVRA is the first and only transdermal contraceptive patch on the market in the United States.

14. At or about the time of introducing the subject product to the market, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC.’s patent for its best-selling oral contraceptive, Ortho Tri-Cyclen[®] (hereinafter referred to as “Ortho Tri-Cyclen”), was about to expire.

15. Thus it was priority for the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., to obtain FDA approval of ORTHO EVRA so that it could offset the lost income previously realized from Ortho Tri-Cyclen.

16. The Defendants, by and through their agent(s), servant(s) and/or employee(s), filed a New Drug Application (“NDA”) for ORTHO EVRA with the FDA on or about December 21, 2000, denoted as NDA 21-180.

17. The NDA states that the intended use of ORHOA EVRA is for the prevention of pregnancy.

18. The subject product’s NDA did not include adequate safety data.

19. Notwithstanding the Defendants' assertion in the NDA that ORTHO EVRA was safe for use in the prevention of pregnancy, the Defendants knew or should have known that the subject product was unsafe, defective, unreasonably dangerous, and not fit for its intended purposes.

20. The risk of developing and/or dying from a blood clot is three times as high among women who use ORTHO EVRA compared to women who use traditional oral contraceptive pills.

21. At all times material hereto, and prior to the FDA's approval of the subject product, the Defendants knew or should have known that the risk of developing and/or dying from a blood clot is three times as high among women who use ORHOA EVRA compared to women who use traditional oral contraceptive pills.

22. Prior to the FDA's approval of the NDA for ORHOA EVRA, the only studies specifically examining ORHOA EVRA's effect on humans were Phase III clinical trials funded and conducted by the Defendants.

23. In the aforesaid clinical trials, the subject product caused or contributed to cases of pulmonary embolism and other venous thrombotic injuries.

24. The incidence of embolisms and thrombotic injuries in the aforesaid clinical trials was approximately six times greater than the incidence of such events in a widely used class of oral contraceptives using the hormone levonorgestrel.

25. In recognition of the above-referenced risks, the FDA Medical Officer's Review expressed serious safety concerns regarding ORHOA EVRA when he stated:

Post-marketing surveillance for DVT (Deep Venous Thrombosis) and PE (Pulmonary Embolism) events will be important, as there are potential serious adverse risks (with two cases of pulmonary emboli in the clinical trials) with this new delivery system for contraception.....

ORHOA EVRA, New Drug Application 21-180 Medical Officer's Review (Nov. 20, 2001).

26. The same FDA Medical Officer's Review further stated that:

"[t]he reviewer's primary concern...is the possible increased risk of VTE and or PE associated with the transdermal delivery of norelgestromin (17 deacetyl-norgestimate) for combination hormonal contraception" and wondered if "the transdermal delivery system and the relatively steady-state serum hormone concentrations for 17d-norgestimate and ethinyl estradiol [was] a factor in the two cases of pulmonary emboli seen in the three pivotal studies."

27. Notwithstanding the above, on or about November, 20, 2001, the FDA initially approved ORHOA EVRA for use as a contraceptive to prevent pregnancy.

28. The Defendants aggressively marketed ORHOA EVRA shortly following its approval by the FDA.

29. At all times material hereto, the Defendant failed to properly disclose safety hazards associated with ORHOA EVRA.

30. The package insert accompanying ORHOA EVRA formerly stated that "the contraceptive patch is expected to be associated with similar risks" to that of other hormonal contraceptives, including birth control pills, injectables, implants and the vaginal ring.

31. In the same package insert, however, the Defendants stated that the safety information they provide to consumers is "derived primarily from studies of birth control pills."

32. The package insert for the subject product further stated that, while the subject product and other combination hormonal contraceptives contain both an estrogen and a progestin, "[t]here is no epidemiological data available to determine whether safety and efficacy with the transdermal route of administration would be different than the oral route."

33. The package insert further stated:

- a. "[I]t is unknown if the risk of venous thromboembolism with ORHOA EVRA use is different than with use of combination oral contraceptives"; and
- b. "[I]t is unknown whether ORHOA EVRA is distinct from other combination

hormonal contraceptives with regard to the occurrence of venous and arterial thrombosis.”

34. The package insert accompanying the subject product is misleading.

35. The package insert accompanying the subject product is in direct conflict with the data collected in the Defendants’ clinical studies in that the package insert suggested that the risks associated with the subject product are equivalent to that of oral contraceptives.

36. In the seventeen-month period from April 2002 through September 2003, the FDA logged 9,116 reports of adverse reactions to ORHOA EVRA.

37. By way of comparison, the leading oral contraceptive, Ortho Tri-Cyclen, which has six times as many users as ORHOA EVRA, only generated 1,237 adverse event reports to the FDA during the six-year period from November 1997 through September 2003.

38. From approximately May 1, 2002 through April 30, 2003, there were fort-four adverse events of injury or death associated with the subject product. These incidents related to blood clots and related brain injuries, deep vein thromboses, pulmonary embolisms, strokes, and heart attacks.

39. From approximately May 1, 2002 through April 30, 2003, there were only seventeen adverse events reported to the FDA related to Ortho-Tri-Cyclen for injuries or deaths from blood clots and related brain injuries, deep vein thromboses, pulmonary embolisms, strokes, and/or heart attacks.

40. Notwithstanding the well-documented safety hazards associated with the subject product, the Defendants have never conducted any meaningful post-market surveillance as suggested in the above referenced FDA Medical Officer’s Review.

41. At all times material hereto, the Defendants, by and through their agents, servants and/or employees, failed to adequately warn physicians and consumers, including Plaintiff herein, that the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or

deep vein thrombosis from ORHOA EVRA is significantly higher than the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis while using oral contraceptives.

42. At all times material hereto, the Defendants knew or should have known that the risks of ORHOA EVRA included severe and life threatening complications and side effects.

43. At all times material hereto, the Defendants, by and through their agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed and/or sold the subject product without adequate instructions or warnings of the subject product's serious side effects and unreasonably dangerous risks.

44. At all times material hereto, the Defendants failed to comply or properly comply with Federal law in connection with the subject product.

45. Plaintiff was prescribed and used the subject product from several months.

46. Prior to using ORHOA EVRA, Plaintiff was in good health and able to perform all of her usual and customary activities.

47. On or about August 16, 2004 at age 30, Plaintiff was presented to the emergency room at Lawrence Hospital Center with complaints of shortness of breath, chest pain and dry cough.

48. Diagnostic testing performed on the Plaintiff at the aforementioned facility revealed that Plaintiff suffered from a Pulmonary Embolism and Infarction, among other things.

49. Plaintiff was subsequently admitted to the aforementioned facility and placed on Coumadin therapy.

50. Had the Defendants properly disclosed the risks associated with the subject product, Plaintiff would not have used it.

51. As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the

subject product, Plaintiff suffered severe and permanent physical injuries, including but not limited to Pulmonary Embolism and Infarction, among other things. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses through her lifetime. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

**FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
DEFECTIVE DESIGN**

52. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

53. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling ORTHO EVRA.

54. The subject product is defective and ~~unreasonably~~ dangerous to consumers.

55. ORTHO EVRA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

56. At all times material to this action, ORTHO EVRA was expected to reach, and did reach, consumers in the State of New York and throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

57. At all time material to this action, ORTHO EVRA was designed, developed,

manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, ORTHO EVRA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis, which cause serious, crippling injuries and event death in an unacceptably high number of users;
- b. When placed in the stream of commerce, ORTHO EVRA was defective in design and formulation, making the use of ORTHO EVRA more dangerous than and ordinary consumer would expect, and more dangerous than other risks associated with the other contraceptive medications and similar drugs on the market for the prevention of pregnancy;
- c. The subject product's design defects existed before it left the control of the Defendants;
- d. ORTHO EVRA was insufficiently tested;
- e. ORTHO EVRA caused harmful side effects that outweighed any potential utility; and
- f. ORTHO EVRA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

58. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

59. As a direct and proximate result of the subject product's defective design, Plaintiff suffered severe and permanent injuries, including but not limited to pulmonary embolism and infarction. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

**SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
MANUFACTURING DEFECT**

60. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 59 above as if fully set forth herein.

61. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

62. At all times material to this action, ORTHO EVRA was expected to reach, and did reach, consumers in the State of New York and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

63. At all times material to this action, ORTHO EVRA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, ORTHO EVRA contained manufacturing defects which rendered the product unreasonably dangerous;
- b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;
- c. The subject product was not made in accordance with the Defendants' specifications or performance standards; and
- d. The subject product's manufacturing defects existed before it left the control of the Defendants.

64. As a direct and proximate result of the subject product's manufacturing defects, Plaintiff suffered severe and permanent physical injuries, including but not limited, pulmonary embolism and infarction. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

**THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
FAILURE TO WARN**

65. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 64 above as if fully set forth herein.

66. ORTHO EVRA was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause blood clots, pulmonary emboli, strokes, heart attacks, deep vein thrombosis, and other serious injuries and side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other forms of contraception.

67. Plaintiff was prescribed and used the subjected product for its intended purpose.

68. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

69. The Defendants, as manufacturers and/or distributors of the subject prescription products, are held to the level of knowledge of an expert in the field.

70. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

71. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of blood clots, pulmonary emboli, strokes, heart attacks, deep vein thrombosis, and other serious injuries and side effects.

72. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

73. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

74. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

75. As a direct and proximate result of the subject product's defective and inappropriate warnings, Plaintiff suffered severe and permanent physical injuries, including but not limited to, pulmonary embolism and infarction. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

**FOURTH CAUSE OF ACTION
PRODUCTS LIABILITY
BREACH OF IMPLIED WARRANTY**

76. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 75 above as if fully set forth herein.

77. The Defendants designed, manufactured, marketed, distributed, supplied and sold the subject product for the prevention of pregnancy.

78. At the time that the Defendants manufactured, marketed, distributed, supplied, and/or sold ORTHO EVRA, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

79. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

80. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

81. Due to the Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after she used it.

82. Contrary to the implied warranty for the subject product, ORTHO EVRA was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

83. As a direct and proximate result of the Defendants' breach of implied warranty, Plaintiff suffered severe and permanent injuries, including but not limited to, pulmonary embolism and infarction. Plaintiff was endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

**FIFTH CAUSE OF ACTION
PRODUCTS LIABILITY
NEGLIGENCE**

84. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 83 above as if fully set forth herein.

85. At all times material hereto, the Defendants, and each of them individually, had a duty to exercise reasonable care to customers, including Plaintiff herein, in the design, development, manufacturing, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of ORTHO EVRA.

86. The Defendants, and each of them individually, breached their duty of reasonable care to Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold the subject product.

87. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants' as follows:

- a. In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of the subject product;
- b. In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of said product's dangerous and defective characteristics;
- c. In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for the subject product;
- d. In its promotion of the subject product in an overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

- e. In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;
- f. In failing to perform appropriate pre-market testing of the subject product;
- g. In failing to perform approximate post-market testing of the subject product; and
- h. In failing to perform appropriate post-market surveillance of the subject product.

88. The Defendants knew or should have known that consumers such as Plaintiff herein would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

89. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical injuries, including but not limited to pulmonary embolism and infarction. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical treatment and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

**SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY**

90. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 89 above as if fully set forth herein.

91. Defendants expressly warranted that ORTHO EVRA was safe and fit for use by consumers and users including Plaintiff for its intended purpose, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

92. At the time of the making of the express warranties, Defendants knew or should have known of the purpose for which ORTHO EVRA was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose.

93. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that ORTHO EVRA was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

94. Members of the medical community, including, but not limited to, Plaintiff's physicians, reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in prescribing, recommending and/or dispensing ORTHO EVRA.

95. Plaintiff relied on the Defendants' ~~express warranties~~.

96. Defendants breached said express warranties, in that ORTHO EVRA was not safe and fit for its intended use and, in fact, causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

97. As a direct and proximate result of the Defendants' breach of express warranty, Plaintiff suffered severe and permanent physical injuries, including but not limited to pulmonary embolism and infarction. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in

the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief and the Court deems just and proper.

WHEREFORE, Plaintiff prays for relief as follows: Five Million Dollars (\$5,000,000.00) on each Cause of Action for a total of Thirty Million Dollars (\$30,000,000.00):

FIRST CAUSE OF ACTION: STRICT PROCUTS LIABILITY DEFECTIVE DESIGN
(\$5,000,000.00)

SECOND CAUSE OF ACTION: STRICT PRODUCTS LIABILITY
MANUFACTURING DEFECT
(\$5,000,000.00)

THIRD CAUSE OF ACTION: STRCT PRODCUTS LIABILITY FAILURE TO WARN
(\$5,000,000.00)

FOURTH CAUSE OF ACTION: PRODCUTS LIABILITY BREACH OF IMPLIED
WARRANTY
(\$5,000,000.00)

FIFTH CAUSE OF ACTION: NEGLIGENCE
(\$5,000,000.00)

SIXTH CAUSE OF ACTION: PRODUCTS LIABILITY BREACH OF EXPRESS
WARRANTY
(\$5,000,000.00)

WHEREFORE, plaintiff demands judgment for compensatory and punitive damages against the defendant herein on all Causes of Actions in an amount that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction over this action, together with the interest, costs and disbursements of same allowed by law.

WHEREFORE, Plaintiff demands trial by jury on all issues to be tried.

Dated: New York New York
August 13, 2007

Yours, etc.,

A handwritten signature in black ink, appearing to read 'C. LoPalo', written over a horizontal line.

Christopher R. LoPalo
NAPOLI BERN RIPKA & ASSOCIATES, LLP
115 Broadway, 12th Floor
New York, NY 10006
(212) 267-3700 - phone
(212) 587-0031 - fax

ATTORNEY VERIFICATION

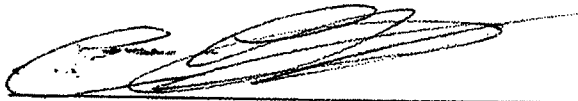
CHRISTOPHER R. LOPALO, an attorney at law, duly admitted to practice in the Courts of the State of New York, affirms under the penalties of perjury that:

He is the attorney for the plaintiff(s) in the above entitled action. That he has read the foregoing VERIFIED COMPLAINT and knows the contents thereof, and upon information and belief, believes the matters alleged therein to be true.

The reason this Verification is made by deponent and not by the plaintiff(s) is that the plaintiff(s) herein reside(s) in a county other than the one in which the plaintiff's attorneys maintain their office.

The source of deponent's information and the grounds of his belief are communications, papers, reports and investigation contained in the file.

Dated: New York, New York
August 13, 2007

A handwritten signature in black ink, appearing to read 'Christopher R. LoPalo', written over a horizontal line.

Christopher R. LoPalo, Esq.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF WESTCHESTER

RENEE MASCUNANA

Index No.:

Plaintiff,

-against-

JOHNSON & JOHNSON, JOHNSON & JOHNSON
PHARMACEUTICAL RESEARCH & DEVELOPMENT,
L.L.C. f/k/a R.W. JOHNSON PHARMACEUTICAL
RESEARCH INSTITUTE, and ORTHO-MCNEIL
PHARMACEUTICAL, INC.

Defendants.

NAPOLI BERN RIPKA & ASSOCIATES, LLP

Attorneys for : Plaintiff
115 Broadway, 12th Floor
New York, New York 10006
(212) 267-3700

To
Attorney(s) for

Service of a copy of the within
Dated, _____

is hereby admitted.

Attorney(s) for

PLEASE TAKE NOTICE:

☐ **NOTICE OF ENTRY**

that the within is a (certified) true copy of an _____ duly entered in
the office of the clerk of the within named court on _____ 200__.

☐ **NOTICE OF SETTLEMENT**

that an order _____ of which the within is a true copy
will be presented for settlement to the HON. _____ one of the judges of
the
within named Court, at _____ on
200__ at _____ O'clock ____ M.

Dated, _____

Yours, etc.

NAPOLI BERN RIPKA & ASSOCIATES, LLP